UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 17, 2017

MEMORANDUM

Subject: Efficacy Review for Sodium Chlorite Technical;
EPA Reg. # 90094-1;
DB Barcode: D442135.
Submission # 1007007.

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Applicant: DRS Laboratories, Inc.
9205 NW 101st St
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Formulation from the Label:

Active Ingredients	% by wt.
Sodium Chlorite*	80 %
Other Ingredients	20 %
Total	100 %

*Available Chlorine……125%

I. BACKGROUND

The product, Sodium Chlorite Technical (EPA Reg. no. 90094-1), is an EPA-approved industrial use only product to generate chlorine dioxide gas for water treatment. The applicant requested an amendment to the registration of this product to add use of this product to generate gaseous Chlorine dioxide for use in the registrant's Mini-CD System® to sterilize biological safety cabinets. Study was generated at DRS Laboratories Inc, located at 450 Allentown Drive, Allentown, PA 18109; and Azzur Labs LLC., located at 4125 Independence Drive, Suite 5, Schnecksville, PA 18078.

This data package identified as D442135 contained a letter from the applicant's representative to EPA (dated August 2, 2017), one study (MRID Nos. 503445-01), Statement of No Data Confidentiality for the study, and Mini-CD System's Instruction Manual (Version 7.2017).

II. LABEL CLAIMS

CD Generation Part A, sodium chlorite, is for use with DRS Laboratories' CD gas generating equipment only. Under the appropriate conditions, the final generated product is chlorine dioxide (CD) gas, which is a strong oxidizer that effectively [decontaminates] [sterilizes] [fumigates] under prescribed conditions of use of DRS CD gas generating equipment. Read and follow this product's label and the appropriate DRS Equipment Instruction Manual for operating procedures of the DRS equipment.

This method of CD gas generation utilizes CD Generation Part A in cold tap water solution with addition of CD Generation Part B, a solid acid, to generate CD gas that will be used to [decontaminate] [sterilize] [fumigate] confined contaminated spaces.

Read and follow the appropriate DRS equipment Instruction Manual for complete instructions for:

- Methods of measuring CD gas at use concentrations and surrounding ambient concentrations,
- Cleaning, sealing, and use of this product in validated and non-validated applications, and
- Instructions on development of an appropriate decontamination, sterilization or fumigation plan.

For DRS's Mini-CD system (MCS), the following procedures will ensure that the conditions of NSF/ANSI Standard 49 and EPA validation criteria for decontamination, sterilization or fumigation of all types and components of the biological safety cabinets (BSC's) are met or exceeded:

1. Relative humidity should be monitored and maintained within a range of 60% to 85% RH throughout the decontamination, sterilization or fumigation process and temperature range should be 59-104°F (15-40°C).
2. Generation rate and times shall be at the specified as per volume of the BSC under decontamination, sterilization or fumigation. Determine and annotate the overall volume contained by the BSC enclosure. Multiply the BSC volume by 0.13 g/ft^3 (4.7 g/m^3) to determine the mass of ClO_2 required to be generated. Divide the mass of ClO_2 value by 0.167 for volumes <25 ft^3 or by 0.245 for volumes >25 ft^3, which is the grams of ClO_2 yielded per gram of CD Generation Part "A", in order to determine the grams of this product required for the decontamination, sterilization or fumigation.
3. The direction of the decontaminate sterilant or fumigant injection in conjunction with the sealing parameters shall be in the same direction of the airflows within an operating BSC. To

ensure even distribution of the decontamination chemical and ensures that no potentially contaminated air from within the BSC will be pulled into the decontaminating device before it appropriate contact time; it will only be recirculated via the exhaust HEPA filter, as to rely on for personal and surrounding environmental protection.

4. Circulation or internal distribution rates and times shall be specified in order to ensure a uniform concentration of the decontaminant, sterilant or fumigant throughout the BSC. Periodically operate the BSC's internal blower to assist circulation. The MCS generation provides a means to assist circulation of the decontaminating, sterilization or fumigation agent in the event of a non-operating BSC to ensure a uniform concentration.

5. Exposure times shall include start and end of the exposure period.

6. Final concentration shall be provided within the BSC, by which the chemical concentration within the BSC was monitored throughout the decontamination validation process.

7. Neutralization or aeration, scrubbing/venting rates and times provided to remove or render harmless the decontaminant used.

Alternatively, you may use the following table to determine the number of pre-weighed (20 gram) packets of CD Generation Part "A" required in the MCS.

Volume ft^3 (m^3)	BSC Size Width - ft^3 (m^3)	CD Generation Chemicals (packets)*
0 (0.0) to 25 (0.7)	0-2 ft. (0.00-0.60)	1 each of A & B
25 (0.7) to 60 (1.7)	3-4 ft. (0.91-1.22)	2 each of A & B
60 (1.7) to 90 (2.5)	5-6 ft. (1.52-1.83)	3 each of A & B
90 (2.5) to 120 (3.4)	n/a – special situation	4 each of A & B

*NOTE: To be used in 500 ml of cold tap water

Only personnel trained to use our DRS CD gas generators may use this product with the mandatory use of the safety equipment specified in the relevant DRS Instruction Manual. All personnel directly involved in the [decontamination] [sterilization] [fumigation] procedure must be familiar with the guidance pertaining to use of CD gas for laboratory and laboratory equipment decontamination in "Biosafety in Microbiological and Biomedical Laboratories" (U.S. DHHS, PHS, CDC, NIH, current edition) and in "NSF/ANSI Standard 49, Annex G" (current edition).

Approved Uses: CD Generation Part "A" is accepted for use to generate CD gas used to [decontaminate] [sterilize] [fumigate] non-porous and porous (HEPA filters) surfaces in sealed enclosures, confined spaces, rooms or areas, structures, buildings, or vehicles located in government, industrial, manufacturing, fermentation, commercial and institutional microbiological laboratory settings, including human and animal research facilities and areas, cleanrooms; animal isolation rooms, necropsy suites, pass throughs, airlocks, and decontamination chambers; biological safety cabinets, glove boxes, isolators, incubators, animal cages and devices, laboratory equipment, supply and exhaust filter systems, and HEPA filtered devices.

DRS's Chlorine Dioxide gas generation system is unaffected by the size or location of the ultimate destination for the CD gas. The CD gas is intended for use to [decontaminate] [sterilize] [fumigate] enclosures up to 120 cubic feet (validated) or greater (non-validated). Uses other than those specified in the appropriate DRS equipment Instruction Manual are not permitted and may not be effective. Review and follow all DRS equipment Instruction Manual instructions and precautions on how to properly utilize this product.

It is strongly recommended that at least *Bacillus atrophaeus* biological indicator (BI) strips be used to confirm each decontamination, sterilization or fumigation has been successful. If one or more of the *Bacillus atrophaeus* BI strips show growth in appropriate media after the decontamination, sterilization or fumigation treatment, the treatment has failed and should be repeated. Do not use this product to treat enclosures over 90 cubic feet (validated use area) without development of an appropriate decontamination, sterilization or fumigation plan that includes validation with BI's. Read and follow the appropriate DRS Instructions for instructions regarding development of an appropriate plan.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Sterilants for Porous and Non-Porous Surfaces within Sealed Enclosures and Vehicles (for Bacterial Spores Known to be Highly Resistant to Sterilants and Disinfectants)

The effectiveness of a sterilant within a sealed enclosure or vehicle may be supported by efficacy data from in-use testing (i.e., field testing) conducted according to an EPA-approved protocol such as "Proposed Protocol to Support Use of EPA Reg. No. 90094-1 with the Mini Chlorine Dioxide System (MCS) to Sterilize/Decontaminate Confined Areas, Specifically Including Biological Safety Cabinets." A protocol was approved by the agency under DP Barcode D427009 and supported by MRID 496749-01. Biological Indicators (BIs) must show no growth for the marker organism after 7 days. Chemical indicators/detectors must show adequate level of Chlorine Dioxide gas. The Chlorine Dioxide concentration in the spaces adjacent to the enclosure exterior or vehicle exterior must remain below 0.1 ppm during the sterilization cycle. Parameters for product application (i.e., temperature, relative humidity, vaporized hydrogen peroxide concentration, contact time) must be met for all four phases of the sterilization cycle.

IV. BRIEF DESCRIPTION OF THE DATA

1. MRID 503445-01 "Study to Support the Use of EPA Reg. No. 90094-1 with the Mini Chlorine Dioxide System (MCS) to Sterilize/Decontaminate Confined Areas, Specifically Including Biological Safety Cabinets" by Michael Regits and Abby Roth. Completion date – December 7, 2016. Repot Date - 20 July 2017. Study conducted at DRS Laboratories Inc. and Azzur Labs LLC. Azzur Labs Laboratory Project Number 170939.

The study was conducted against spores of *Bacillus atropheus* (ATCC # 9372) and *Geobacillus stearothermophilus* (ATCC # 7953) on cellulose strips (representing porous surfaces) and stainless steel discs (representing hard nonporous surfaces). Three replicates were run on three different lots (60 carriers/organism /surface type) of sodium chlorite technical, EPA reg. No. 90094-1; representing a total of 720 biological indicators. The sodium chlorite (also called CD Generation Part A) was reacted with sodium bisulfite (also called CD Generation Part B) to produce chlorine dioxide and it is the chlorine dioxide that was tested for efficacy against the spores of the organisms. Cold tap water at 200 ppm hardness was used for production of CD gas. Each replicate involved 60 carriers/organism/surface type. The chlorine dioxide was generated and administered according to owner's manual and was tested at the LCL of 50.44 grams (part A) and 75.66 grams (part B) for a volume of 78 ft^3. The biological indicators were placed in HEPA filtered biological safety cabinets with motor turned off. Indicators were also placed on and under work, motor blades, positive and negative pressure areas surfaces, rear wall, and exhaust (28 locations). Positive controls (unexposed biological indicators) and negative controls (Unopened

tubes of tryptic soy broth) were used for each replicate. After treating the room for a period of 90-150 minutes, the chlorine dioxide gas was removed from the room (to below 0.1 ppm chlorine dioxide gas). After the scrubbing cycle, all the Bl's were immediately aseptically transferred into the neutralizing subculture media tubes (Tryptic Soy Broth (TSB) with 0.08% sodium thiosulfate) on site (DRS Laboratories) by Azzur Labs. All test samples were transferred before the positive controls. *Geobacillus stearothermophilus* carriers were incubated at 55°C to 60°C. *Bacillus atrophaeus* carriers were incubated at 30°C to 35°C. The tubes were visually inspected for turbidity at 24 hours to 4 days. The tubes were returned to the appropriate incubator. Visual inspection of the tubes for turbidity was done after at least seven days of incubation.

Note: In the third replicate, 2/60 carriers were positive for *Bacillus atropheus* on stainless steel and 1/60 carriers was positive for *Geobacillus stereothermopillus* on cellulose. After consultation with EPA, the study was repeated for organisms on the media which provided positive results. This constituted a fourth study run.

V. RESULTS

MRID # 503445-01

Lots Set A/B	Organisms	Carrier Types	No. Exhibiting Growth/Total No. Tested	Carrier Counts (CFU/ carrier)
386DDBZ 162/ K27422	*Bacillus atropheus* (ATCC # 9372)	Cellulose	0/60	2.8×10^6
		Stainless Steel	0/60	
	Geobacillus stearothermophilus (ATCC # 7953)	Cellulose	0/60	1.8×10^6
		Stainless Steel	0/60	
386DDGY 133/ K29302A	*Bacillus atropheus* (ATCC # 9372)	Cellulose	0/60	2.8×10^6
		Stainless Steel	0/60	
	Geobacillus stearothermophilus (ATCC # 7953)	Cellulose	0/60	1.8×10^6
		Stainless Steel	0/60	
386BDBA 181/ WA19626B	*Bacillus atropheus* (ATCC # 9372)	Cellulose	0/60	2.7×10^6
		Stainless Steel	2/60	
	Geobacillus stearothermophilus (ATCC # 7953)	Cellulose	1/60	2.1×10^6
		Stainless Steel	0/60	
386BDBA 181/ WA19626B	*Bacillus atropheus* (ATCC # 9372)	Stainless Steel	0/60	1.3×10^6
	Geobacillus stearothermophilus (ATCC # 7953)	Cellulose	0/60	1.9×10^6

VI. CONCLUSION

1. The submitted data **support** the use of the product, Sodium Chlorite Technical (EPA Reg. No. 90094-1), use as “Part A” in the generation of chlorine dioxide gas as delivered by the DRS Laboratories’ Mini-CD System (MCS), as sterilant of Biological Safety Cabinets (BSCs) on porous and non-porous surfaces, when used at 0.667g/ft3 Sodium Chlorite (Part A), 1.0g/ft3 Part B [to generate 0.13g/ft3 (4.7g/m3) chlorine dioxide gas], with BSC’s internal blower “off”, in 90-150 minutes cycles, under 60-85% relative humidity and 59-104°F (15-40°C).

VII. LABEL

1. The proposed label claims **are acceptable** regarding the use of the product, Sodium Chlorite Technical (EPA Reg. No. 90094-1) as "Part A", with a "Part B", in the generation of 0.13 g/ft^3 (4.7 g/m^3) chlorine dioxide gas, delivered by the DRS Laboratories' Mini-CD System (MCS), for 90-150 minutes cycles, under 60-85% relative humidity and 59-104°F (15-40°C), to effectively decontaminate/sterilize/fumigate, non-porous and porous (HEPA filters) surfaces in sealed enclosures such as biological safety cabinets (BSC's).

Registrant generated data under conditions which simulated a defective/powered off BSC internal blower but did not include this condition in the use directions on the label.

2. The applicant must make the following changes to the proposed label, as appropriate:

- On page 1, remove "Water Treatment Applications: Available Chlorine…..125%" as the statement could not be justified.

- On page 3, add instruction for sterilizing BSCs **when internal blower is defective** or operating without the BSC's internal blower to assist circulation.

- On page 3, revise the statement "The direction of the decontaminate sterilant or fumigant…" to "The direction of the decontaminant, sterilant or fumigant…" In addition, revise "To ensure even distribution of the decontamination chemical and ensures that no…." to "To ensure even distribution of the decontamination chemical and ensure that no…."

- On page 5 of the label under the "Food Plant Process Water Treatment" heading and page 6 under the "Bacterial Slime Control in Paper Mills" heading, qualify "microbiological growth" as non-public health or non-pathogenic.